

AMENDMENTS TO THE CLAIMS

Listing of Claims:

Claim 1 (currently amended): A process for preparing a pharmaceutical composition comprising as an active ingredient a hygroscopic salt of valproic acid, comprising the step of intimately mixing (i) said hygroscopic salt; (ii) a carbomer and (iii) a non-hygroscopic additive to form a homogeneous mixture; wherein the amount of said carbomer and said non-hygroscopic additive are sufficient relative to the amount of said hygroscopic salt to produce said mixture having the following property: when compressed into tablets, said tablets do not absorb more than 5% water by weight when tested after being stored for 3 months at 75% relative humidity; and wherein said pharmaceutical composition is free of valproic acid.

B1

Claim 2 (original): The process of claim 1, wherein said hygroscopic salt of valproic acid is sodium valproate.

Claim 3 (original): The process of claim 1, wherein the weight ratio of carbomer to the hygroscopic salt of valproic acid ranges from about 1:3 to about 1:100.

Claim 4 (original): The process of claim 1, wherein the weight ratio of carbomer to the hygroscopic salt of valproic acid ranges from about 1:3 to about 1:10.

Claim 5 (original): The process of claim 1, wherein the weight ratio of non-hygroscopic additive to the hygroscopic salt of valproic acid ranges from about 1:6 to about 1:2.

Claim 6 (original): The process of claim 1, further comprising a step of adding at least one excipient to the mixture of said hygroscopic salt, said carbomer and said non-hygroscopic additive.

Bd

Claim 7 (currently amended): The process of claim 1, further comprising a step of directly compressing said non-hygroscopic composition into a solid dosage form.

Claim 8 (original): The process of claim 7, wherein said solid dosage form contains from about 50 to about 1200 mg of sodium valproate.

Claim 9 (original): The process of claim 8, wherein said solid dosage form contains from about 6 mg to about 400 mg of carbomer.

Claim 10 (original): The process of claim 9, wherein, said solid dosage form contains from about 90 mg to about 400 mg of non-hygroscopic additive.

Claim 11 (original): The process of claim 3, wherein said non-hygroscopic additive is selected from the group consisting of dibasic calcium phosphate anhydrous, calcium silicate, microcrystalline cellulose and mixtures thereof.

B1

Claim 12 (original): The process of claim 3, wherein said non-hygroscopic additive is present in an amount such that the weight ratio of non-hygroscopic additive to the hygroscopic salt of valproic acid is in the range of from about 1:6 to 1:2.

Claim 13 (original): The process of claim 6, wherein said excipient is selected from the group consisting of lubricants, disintegrators, glidants, adsorbents, and mixtures thereof.

Claim 14 (original): The process of claim 13, wherein said lubricant is selected from the group consisting of stearic acid, a salt of stearic acid, talc, sodium lauryl sulfate, sodium stearyl fumarate and mixtures thereof.

Claim 15 (original): The process of claim 14, wherein said lubricant is present in an amount of from about 0.25% to about 5% of the weight of the final composition.

B1

Claim 16 (original): The process of claim 13, wherein said disintegrator is selected from the group consisting of crosscarmellose sodium, sodium starch glycolate, starch, magnesium aluminum silicate, colloidal silicon dioxide, carboxymethyl cellulose, microcrystalline cellulose, and mixtures thereof.

Claim 17 (original): The process of claim 16, wherein said disintegrator is present in an amount of from about 0.5% to about 25% of the weight of the final composition.

Claim 18 (original): The process of claim 12, wherein said glidant is selected from the group consisting of colloidal silicon dioxide, talc and mixtures thereof.

Claim 19 (original): The process of claim 18, wherein said glidant is present in an amount of from about 0.1 % to about 10% of the weight of the final composition.

Claim 20 (original): The process of claim 13, wherein said adsorbent is selected from the group consisting of colloidal silicon dioxide, microcrystalline cellulose, calcium silicate and mixtures thereof.

BI

Claim 21 (original): The process of claim 20, wherein said adsorbent is present in an amount of from about 0.05% to about 42% of the weight of the final composition.

Claim 22 (original): The process of claim 7, wherein said solid dosage form is selected from the group consisting of a tablet, a caplet, a pellet, a capsule, a tablet which disintegrates into granules, and a pill.

Claim 23 (original): The process of claim 21, wherein the tablet is an enteric coated tablet.

Claim 24 (original): The process of claim 21, wherein the tablet is coated with an anti-moisture barrier.

Claim 25 (original): The process of claim 1, wherein said mixing is carried out in conditions of relative humidity of greater than 30%.

B1

Claim 26 (currently amended): A non-hygroscopic oral pharmaceutical composition comprising a pharmaceutically effective amount of a hygroscopic salt of valproic acid, a carbomer, and a non-hygroscopic additive, wherein the amount of said carbomer and said non-hygroscopic additive are sufficient relative to the amount of said hygroscopic salt to produce said composition having the following property: not absorbing more than 5% by weight water when tested after being stored for 3 months at 75% relative humidity; and wherein said pharmaceutical composition is free of valproic acid.

Claim 27 (currently amended): A non-hygroscopic oral pharmaceutical composition comprising a pharmaceutically effective amount of a hygroscopic salt of valproic acid, a carbomer, and a non-hygroscopic additive, wherein the amount of said carbomer and said non-hygroscopic additive are sufficient relative to the amount of said hygroscopic salt to produce said composition having the following property: when compressed into tablets, said tablets do not absorb more than 5% by weight water when tested after being stored for 3 months at 75% relative humidity; and wherein said pharmaceutical composition is free of valproic acid.

B1

Claim 28 (original): The pharmaceutical composition of claim 27, wherein said hygroscopic salt of valproic acid is sodium valproate.

Claim 29 (original): The pharmaceutical composition of claim 27, wherein the weight ratio of carbomer to the hygroscopic salt of valproic acid ranges from about 1:3 to about 1:100.

Claim 30 (original): The pharmaceutical composition of claim 27, wherein the weight ratio of carbomer to the hygroscopic salt of valproic acid ranges from about 1:3 to about 1:10.

Claim 31 (original): The pharmaceutical composition of claim 29, wherein the non-hygroscopic additive is present in an amount such that the weight ratio of non-hygroscopic additive to the hygroscopic salt of valproic acid is in the range of from about 1:6 to about 1:2.

B1
Claim 32 (currently amended): The pharmaceutical ~~composition~~ composition of claim 31, wherein said non-hygroscopic additive is present in an amount such that the weight ratio of the non-hygroscopic additive to the carbomer is in the range of from about 2:1 to about 35:1.

Claim 33 (original): The pharmaceutical composition of claim 27, further comprising at least one excipient.

Claim 34 (original): The pharmaceutical composition of claim 27, wherein the composition contains from about 50 to about 1200 mg of sodium valproate.

Claim 35 (original): The pharmaceutical composition of claim 34, wherein the composition contains from about 6 mg to about 400 mg of carbomer.

Claim 36 (original): The pharmaceutical composition of claim 35, wherein the composition contains from about 90 mg to about 400 mg of non-hygroscopic additive.

B1 Claim 37 (original): The pharmaceutical composition of claim 27, wherein said non-hygroscopic additive is selected from the group consisting of dibasic calcium phosphate anhydrous, calcium silicate, microcrystalline cellulose and mixtures thereof.

Claim 38 (original): The pharmaceutical composition of claim 27, further comprising an excipient selected from the group consisting of lubricants, disintegrators, glidants, adsorbents, and mixtures thereof.

Claim 39 (original): The pharmaceutical composition of claim 38 wherein said lubricant is selected from the group consisting of stearic acid, a salt of

stearic acid, talc, sodium lauryl sulfate, sodium stearyl fumarate and mixtures thereof.

Claim 40 (original): The pharmaceutical composition of claim 39, wherein said lubricant is present in an amount of from out 0.25% to about 5% of the weight of the final composition.

B1 Claim 41 (original): The pharmaceutical composition of claim 38, wherein said disintegrator is selected from the group consisting of crosscarmellose sodium, sodium starch glycolate, starch, magnesium aluminum silicate, colloidal silicon dioxide, carboxymethyl cellulose, microcrystalline cellulose, and mixtures thereof.

Claim 42 (original): The pharmaceutical composition of claim 41, wherein said disintegrator is present in an amount of from about 0.5% to about 25% of the weight of the final composition.

Claim 43 (original): The pharmaceutical composition of claim 38, wherein said glidant is selected from the group consisting of colloidal silicon dioxide, talc and mixtures thereof.

Claim 44 (original): The pharmaceutical composition of claim 43, wherein said glidant is present in an amount of from about 0.1 % to about 10% of the weight of the final composition.

21

Claim 45 (original): The pharmaceutical composition of claim 38, wherein said adsorbent is selected from the group consisting of colloidal silicon dioxide, microcrystalline cellulose, calcium silicate and mixtures thereof.

Claim 46 (original): The pharmaceutical composition of claim 45, wherein said adsorbent is present in an amount of from about 0.05% to about 42% of the weight of the final composition.

Claim 47 (original): The pharmaceutical composition of claim 27, wherein the non-hygroscopic oral pharmaceutical composition is a tablet, a caplet, a pellet, a capsule, a tablet which disintegrates into granules, and a pill.

Claim 48 (original): The pharmaceutical composition of claim 47, wherein the tablet is an enteric coated tablet.

Claim 49 (original): The pharmaceutical composition of claim 48, wherein the tablet is coated with an anti-moisture barrier.

B1

Claim 50 (currently amended): The pharmaceutical composition of claim 27, wherein the non-hygroscopic oral pharmaceutical composition is a sustained release tablet ~~wherein the weight ratio of carbomer to the hygroscopic salt of valproic acid ranges from about 1:6 to about 1:20.~~

Claim 51 (currently amended): The pharmaceutical composition of claim 50, ~~wherein the non-hygroscopic oral pharmaceutical composition is a sustained release tablet~~ wherein the weight ratio of carbomer to the hygroscopic salt of valproic acid ranges from about 1:6 to about 1:20.

B1
Claim 52 (currently amended): A method of treating a medical condition in a human patient, the method comprising the step of orally administering a non-hygroscopic pharmaceutical composition for release of a salt of valproic acid into the bloodstream at a physiologically effective level, wherein said composition comprises a pharmaceutically effective amount of a hygroscopic salt of valproic acid, a ~~carrier~~ carbomer, and a non-hygroscopic additive, and wherein the weight ratio of the carbomer to the hygroscopic salt of valproic acid is from about 1:3 to about 1:100 and the weight ratio of the non-hygroscopic additive to the hygroscopic salt of valproic acid is from about 1:6 to about 1:2; and wherein said pharmaceutical composition is free of valproic acid.

Claim 53 (original): The method of claim 52, wherein said medical condition is epilepsy.

Claim 54 (original): The method of claim 52, wherein said medical condition is a psychotic disorder.

Claim 55 (original): The method of claim 52, wherein said medical condition is a migraine headache.

Claim 56 (new): The method of claim 1 wherein the weight ratio of the carbomer to the hygroscopic salt of valproic acid ranges from about 1:3 to about 1:100, and the weight ratio of the non-hygroscopic additive to the hygroscopic salt of valproic acid ranges from about 1:6 to about 1:2.

B1 Claim 57 (new): The method of claim 56 further comprising a step of directly compressing the composition into a solid dosage form.

Claim 58 (new): The composition of claim 27, said composition having been formed into a solid dosage form by direct compression.